MAR 2 2 2013

510(k) SUMMARY
MEDTRONIC Sofamor Danek
MRI Update for PEEK Interbody Fusion Devices
July 2012

I. Company:

Medtronic Sofamor Danek,
USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. Contact:

Becky Ronner
Regulatory Affairs Specialist
Telephone: (901) 399-2757
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III. Proprietary Trade Name:

Cervical Interbody Fusion Devices
ANATOMIC PEEK Cervical Fusion System
CORNERSTONE® PSR Cervical Fusion System
PEEK PREVAIL® CERVICAL INTERBODY DEVICE

Lumbar Interbody Fusion Devices
CAPSTONE® CONTROL Spinal System
CLYDESDALE® Spinal System
CRESCENT® Spinal System (PEEK)
SOVEREIGN® Spinal System
TELAMON® PEEK Spinal System

IV. Common &Classification Names:

Cervical & Lumbar Interbody Fusion Devices

Class:

II

Product Code:

ODP (21 CFR 888.3080)	ANATOMIC PEEK Cervical Fusion System CORNERSTONE® PSR Cervical Fusion System
OVE (21 CFR 888.3080)	PEEK PREVAIL® CERVICAL INTERBODY DEVICE
MAX (21 CFR 888.3080)	CAPSTONE® CONTROL Spinal System CLYDESDALE® Spinal System CRESCENT® Spinal System (PEEK) TELAMON® PEEK Spinal System
OVD (21 CFR 888.3080)	SOVEREIGN® Spinal System

V. Description:

a. ANATOMIC PEEK Cervical Fusion Implants

The ANATOMIC PEEK Cervical Fusion Implants consists of cages of various widths and heights which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. These implants are manufactured from implant grade polyetheretherketone (PEEK). The hollow geometry of the implants allows them to be packed with autogenous bone graft in cervical interbody fusion procedures. The ANATOMIC PEEK devices are intended to be implant via an open anterior approach and used with supplemental fixation and autogenous bone graft.

b. CORNERSTONE® PSR Cervical Fusion Implants

The CORNERSTONE® PSR Cervical Fusion Implants consist of cages of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. These implants are manufactured from implant grade PEEK. The hollow geometry of the implants allows them to be packed with autogenous bone graft in cervical fusion procedures. The CORNERSTONE® PSR device is to be used with supplemental instrumentation and is to be implanted via an open, anterior approach.

c. **PEEK PREVAIL™ Cervical Interbody Device**

The PEEK PREVAIL™ Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is "I-Beam" shaped with a 2 screw midline configuration. This device is intended to be radiolucent and the interior space of the product is to be used with autograft.

The PEEK PREVAIL™ Cervical Interbody device implant is manufactured from PEEK and contains tantalum radiopaque markers and a Nitinol screw locking mechanism. The screws used with this device (ZEPHIR® Anterior Cervical Screws) are manufactured from Titanium Alloy.

d. **CAPSTONE® CONTROL Spinal System Implants**

The CAPSTONE CONTROL™ Spinal System Implants consist of PEEK cages of various widths and heights which include Tantalum markers. These implants can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The CAPSTONE CONTROL™ Spinal System Implants are to be used with supplemental instrumentation and are to be implanted via an open or minimally invasive, posterior or transforaminal approach.

e. **CLYDESDALE® Spinal System Implants**

The CLYDESDALE® Spinal System Implants consist of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted via a lateral approach between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The CLYDESDALE® Spinal System Implants are to be used with supplemental instrumentation.

f. **CRESCENT® Spinal System (PEEK) Implants**

The CRESCENT® Spinal System Implants consist of PEEK cages of various widths and heights which include Tantalum markers. These implants can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The implants may be implanted via a posterior, transforaminal or lateral approach and the procedure may be open or minimally invasive. The CRESCENT® Spinal System Implants are to be used with supplemental instrumentation.

g. **SOVEREIGN® Spinal System Implants**

The SOVEREIGN® Spinal System Implants are an intervertebral body fusion devices with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is lens-shaped with three holes for placement of titanium screws. The SOVEREIGN® Spinal System contains both a fixed and a variable angle screw option. The fixed angle screw option provides an interference fit with the PEEK interbody implant. The variable angle screw option provides a slight clearance between the PEEK interbody implant and the screw which allows for a small amount of variable screw angulation. This system is intended to be radiolucent and the interior space of the product is to be used with autogenous bone graft. The accompanying cover plate is designed to resist screw backout and must be used when the variable angle screws are implanted.

The SOVEREIGN® Spinal System interbody device is manufactured from PEEK and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.

h. TELAMON® PEEK Spinal System Implants

The TELAMON® PEEK Spinal System Implants consist of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. These implants may be implanted via an open or a minimally invasive posterior approach. The TELAMON® PEEK Spinal System Implants are to be used with supplemental instrumentation.

VI. Indications for Use:

a. ANATOMIC PEEK Cervical Fusion Implants

The ANATOMIC PEEK device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK device is to be used with supplemental fixation. The ANATOMIC PEEK device is also required to be used with autograft and is to be implanted via an open, anterior approach.

b. CORNERSTONE® PSR Cervical Fusion Implants

The CORNERSTONE® PSR device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by

radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with autograft.

c. PEEK PREVAIL™ Cervical Interbody Device

The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The PEEK PREVAIL™ Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL™ Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

d. CAPSTONE® CONTROL Spinal System Implants

The CAPSTONE CONTROL™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants

are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

e. **CLYDESDALE® Spinal System Implants**

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. **These implants may be implanted via a minimally invasive lateral approach.**

f. **CRESCENT® Spinal System (PEEK) Implants**

The CRESCENT® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

g. **SOVEREIGN® Spinal System Implants**

The SOVEREIGN® Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain

with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach.

The SOVEREIGN® interbody system may be used as a stand-alone device or in conjunction with supplemental fixation.

When used as a stand-alone device, the SOVEREIGN® interbody device is intended to be used with the three titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation for use in the lumbar spine must be used to augment stability.

h. TELAMON® PEEK Spinal System Implants

The TELAMON® PEEK Spinal System is indicated for interbody fusion with autogenous bone graft in patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

VII. Summary of the Technological Characteristics:

The purpose of this bundled 510(k) application is to provide appropriate MRI safety labeling for the subject devices, while also providing MRI technologists with a method of concluding whether an MRI scan can be performed on the device and specific instructions on how to perform the scan. The systems in this 510(k) submission have been determined to be MR conditional per ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

The labeling that is being proposed has previously been cleared by FDA in submission K110063 for SOVEREIGN® Spinal System Implants. All the subject devices within this bundled submission have the same fundamental technology. They are intended to provide correction and stabilization during intervertebral body fusion procedures for treatment of degenerative disc disease. They are all generally manufactured from the same PEEK and tantalum materials and have been designed to be used with autogenous bone graft. There have been no changes to the design, to the material or the indications of the subject devices and are therefore identical to their predicates.

The design/specifications of the subject devices are not being addressed. No changes have occurred for the devices in the subject product families which are considered substantially equivalent to and previously cleared under previous 510(k) submissions such as:

a. **ANATOMIC PEEK Cervical Fusion System**
   K112444 (SE 11/15/2011)
b. **CORNERSTONE® PSR Cervical Fusion System**
   K100214 (SE 06/25/2010), K111264 (SE 10/12/2011)
c. **PEEK PREVAIL® Cervical Interbody Device**
   K073285 (SE 05/15/2008), K094042 (SE 06/30/2010), K113252 (SE 01/17/2012), K030327(SE 02/26/2003)
d. **CAPSTONE® CONTROL Spinal System**
   K120368 (04/09/2012)

e. **CLYDESDALE® Spinal System**
K113528 (SE 12/20/2011), K100175 (SE 06/02/2010), K083026 (SE 12/29/2008)

f. **CRESCENT® Spinal System (PEEK)**
K094025 (SE 04/26/2010)

g. **SOVEREIGN® Spinal System**
K091813 (SE 11/17/2009), K110063 (SE 10/04/2011)

h. **TELAMON® PEEK Spinal System**
K110562 (SE 11/09/2011)

IX. Discussion of Non-Clinical Testing:

In accordance FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" testing has been completed on the worst case implants. The following testing has been completed and provided a determination that the subject devices in this 510(k) submission have been determined to be MR conditional:

- ASTM F2052 – "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment"
- ASTM F2213 – "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment"
- ASTM F2119 – "Standard test method for evaluation of MR image artifacts from passive implants"
- ASTM F2182 – "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging"
- ASTM F2503 – "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment"

X. Conclusion:

Non-clinical testing in accordance with the standards listed above was completed along with a risk analysis. Based on the test results and additional

supporting documentation provided within this pre-market notification, Medtronic believes that the subject devices demonstrate substantial equivalence to the listed predicate device and should be labeled as MR Conditional in accordance with ASTM F2503 – "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 22, 2013

Medtronic Sofamor Danek USA, Incorporated
% Ms. Becky Ronner
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K122037
Trade/Device Name: ANATOMIC PEEK CERVICAL FUSION SYSTEM
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, OVE, OVD
Dated: February 20, 2013
Received: February 21, 2013

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K122037

Device Name: ANATOMIC PEEK CERVICAL FUSION SYSTEM

Indications for Use:

The ANATOMIC PEEK CERVICAL FUSION SYSTEM is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK CERVICAL FUSION SYSTEM is to be used with any cleared supplemental fixation device for cervical. The ANATOMIC PEEK CERVICAL FUSION SYSTEM is also required to be used with autogenous bone graft and is to be implanted via an open, anterior approach."

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K122037

Device Name: CORNERSTONE® PSR Cervical Fusion System

Indications for Use:

The CORNERSTONE® PSR device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with autograft.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K122037

Device Name: PEEKPREVAIL® Cervical Interbody Device

Indications for Use:

The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The PEEK PREVAIL™ Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL™ Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K122037

Device Name: CAPSTONE® CONTROL Spinal System

Indications for Use:

The CAPSTONE CONTROL™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K122037

Device Name: CLYDESDALE® Spinal System

Indications for Use:

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. **These implants may be implanted via a minimally invasive lateral approach.**

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K122037

Device Name: CRESCENT® Spinal System (PEEK)

Indications for Use:

The CRESCENT® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K122037

Device Name: SOVEREIGN® Spinal System

Indications for Use:

The SOVEREIGN® Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach.

The SOVEREIGN® interbody system may be used as a stand-alone device or in conjunction with supplemental fixation.

When used as a stand-alone device, the SOVEREIGN® interbody device is intended to be used with the three titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation for use in the lumbar spine must be used to augment stability.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K122037

Device Name: TELAMON® PEEK Spinal System

Indications for Use:

The TELAMON® PEEK Spinal System is indicated for interbody fusion with autogenous bone graft in patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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